Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	64	0.1672	(0.1298,0.2045)	82	0.2158	(0.1744,0.2572)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	8	0.0210	(0.0066,0.0354)	13	0.0347	(0.0161,0.0532)
Baker III, IV Capsular Contracture	9	0.0237	(0.0084, 0.039)	15	0.0401	(0.0202, 0.06)
Baker IV Capsular Contracture	1	0.0027	(0,0.0079)	2	0.0054	(0,0.0129)
Breast Mass	0	0.0000	(0, 0)	3	0.0083	(0,0.0176)
Breast Pain	2	0.0053	(0,0.0125)	3	0.0080	(0,0.0171)
Breast Sensation Changes	0	0.0000	(0, 0)	1	0.0027	(0,0.0079)
Delayed Wound Healing	2	0.0052	(0,0.0124)	2	0.0052	(0,0.0124)
External Injury Not Related To Breast Implants	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
Extrusion	2	0.0052	(0,0.0124)	3	0.0079	(0,0.0168)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	2	0.0052	(0,0.0124)	2	0.0052	(0,0.0124)
Implant Malposition/Displacement	2	0.0053	(0,0.0126)	3	0.0080	(0,0.0171)
Infection	9	0.0235	(0.0083,0.0386)	10	0.0261	(0 0101,0.0421)
Inflammation	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	103	0.2791	(0.2328,0.3254)	116	0.3705	(0.3062,0.4348)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	17	0.0467	(0.025,0.0685)	19	0.0568	(0.0312,0.0825)
Baker III, IV Capsular Contracture	19	0.0522	(0.0293,0.0751)	21	0.0623	(0.0357,0.0889)
Baker IV Capsular Contracture	2	0.0054	(0,0.0129)	2	0.0054	(0,0.0129)
Breast Mass	6	0 0170	(0.0035,0.0305)	7	0 0223	(0.0053,0.0393)
Breast Pain	4	0.0110	(0.0003,0.0217)	4	0.0110	(0.0003,0 0217)
Breast Sensation Changes	2	0.0057	(0,0.0135)	2	0.0057	(0,0.0135)
Delayed Wound Healing	2	0.0052	(0,0.0124)	2	0.0052	(0,0.0124)
External Injury Not Related To Breast Implants	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
Extrusion	3	0.0079	(0,0.0168)	3	0.0079	(0,0.0168)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	3	0.0098	(0,0.0212)	3	0.0098	(0,0.0212)
Implant Malposition/Displacement	5	0.0138	(0.0018,0.0258)	5	0.0138	(0.0018,0.0258)
Infection	13	0.0345	(0.0161, 0.053)	13	0.0345	(0.0161, 0.053)
Inflammation	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	1	0.0116	(0,0.0343)

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Metastatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	3	0.0079	(0,0.0168)	4	0.0106	(0.0003, 0.021)
Placement Damage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rash	2	0.0052	(0,0.0124)	2	0.0052	(0,0.0124)
Recurrent Breast Cancer	2	0.0053	(0,0.0126)	3	0.0080	(0,0.0171)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	11	0.0286	(0.012,0.0453)	11	0.0286	(0.012,0.0453)
Suture Reaction	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	9	0.0236	(0.0084,0.0388)	12	0.0317	(0.014,0.0494)
Abnormal Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsular Contracture Secondary To Radiation Therapy	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Capsule Tear	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Cellulitis	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
Distortion Of Breast Shape Not Related To Capsular Contracture	0	0.0000	(0, 0)	1	0.0027	(0,0.0079)
Dog Ear Scars From Mastectomy	2	0.0052	(0,0.0123)	2	0.0052	(0,0.0123)
Ecchymosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excessive Implant Movements	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Metastatic Disease	0	0.0000	(0, 0)	2	0.0263	(0,0.0623)
Necrosis	1	0.0026	(0,0.0077)	2	0.0079	(0,0.0193)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	4	0.0106	(0.0003, 0.021)	5	0.0200	(0,0.0409)
Placement Damage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rash	2	0.0052	(0,0.0124)	2	0.0052	(0,0.0124)
Recurrent Breast Cancer	4	0.0109	(0.0003,0.0215)	4	0.0109	(0.0003,0.0215)
Rupture	1	0.0040	(0,0 0118)	1	0.0040	(0,0.0118)
Seroma	12	0.0316	(0.014,0.0492)	12	0.0316	(0.014,0.0492)
Suture Reaction	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	15	0.0402	(0.0203,0.0602)	17	0.0504	(0.0262,0.0747)
Abnormal Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsular Contracture Secondary To Radiation Therapy	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Capsule Tear	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Cellulitis	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
Distortion Of Breast Shape Not Related To Capsular Contracture	1	0.0027	(0,0.0079)	1	0.0027	(0,0.0079)
Dog Ear Scars From Mastectomy	2	0.0052	(0,0.0123)	2	0.0052	(0,0.0123)
Ecchymosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excessive Implant Movements	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling
Note 3: Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Extra Skin	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	1	0.0027	(0,0.0079)	1	0.0027	(0,0.0079)
Mondor's Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Muscle Spasm	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Nipple Complications	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Nipple Related Unplanned	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pt Requests Removal Due To Personal Reasons	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
Soft Mass Left Costal Margin	0	0 0000	(0, 0)	0	0.0000	(0, 0)
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	0	0.0000	(0, 0)	1	0.0027	(0,0.0081)
Symmastia And Implant Malposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Tight Benilli Suture	0	0.0000	(0, 0)	1	0.0027	(0,0.0081)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Extra Skin	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	1	0.0029	(0,0.0087)	1	0.0029	(0,0.0087)
Loss Of Inframammary Fold	1	0.0027	(0,0.0079)	1	0.0027	(0,0.0079)
Mondor's Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Muscle Spasm	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Nipple Complications	3	0.0082	(0,0.0175)	3	0.0082	(0,0.0175)
Nipple Related Unplanned	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	2	0.0104	(0,0.0246)
Pain - Sternum And Under Left Arm Intermittent	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pt Requests Removal Due To Personal Reasons	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
Soft Mass Left Costal Margin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	1	0.0027	(0,0.0081)	1	0.0027	(0,0.0081)
Symmastia And Implant Malposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Tight Benilli Suture	1	0.0027	(0,0.0081)	1	0.0027	(0,0.0081)

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

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IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication Excluding Cosmetic	46	0.1200	(0 0875,0.1525)	57	0.1497	(0.1139,0.1856)
II. Cosmetic Complication						
Asymmetry	7	0.0184	(0.0049,0.0318)	10	0.0264	(0.0103,0.0426)
Hypertrophic Scarring	8	0.0211	(0.0066,0.0355)	12	0.0321	(0.0142,0.0501)
Ptosis	2	0.0053	(0,0.0127)	4	0.0109	(0.0003,0.0215)
Wrinkling	6	0.0158	(0.0033,0.0284)	7	0.0185	(0.0049,0.0321)
Any Cosmetic Complication	21	0.0553	(0.0323,0.0783)	30	0.0799	(0.0525,0 1074)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

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Table 8 7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication Excluding Cosmetic	76	0.2062	(0.1645,0.2479)	83	0.2672	(0.2065, 0.328)
II. Cosmetic Complication						
Asymmetry	12	0.0321	(0.0142, 0.05)	16	0.0557	(0.0267,0.0847)
Hypertrophic Scarring	13	0.0363	(0.0167,0.0558)	15	0.0463	(0.0225,0.0702)
Ptosis	6	0.0166	(0.0034,0.0298)	12	0.0588	(0.0221,0.0955)
Wrinkling	7	0.0185	(0.0049,0.0321)	8	0.0233	(0.0068,0.0398)
Any Cosmetic Complication	35	0.0954	(0 0652,0.1257)	44	0.1505	(0.1046,0.1965)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

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IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	10	0.0261	(0.0101, 0.042)	26	0.0682	(0.0429,0.0934)
Explant with Replacement with Study Device	7	0.0184	(0.0049,0.0319)	17	0.0450	(0.0241, 0.066)
Explant without Replacement	3	0.0078	(0,0.0166)	9	0.0239	(0.0085,0.0393)
Other Reoperations	24	0.0630	(0.0386,0.0874)	47	0.1247	(0.0913,0.1581)
Biopsy	4	0.0105	(0.0003,0.0208)	6	0.0161	(0.0033,0.0288)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	3	0.0079	(0,0.0169)	8	0.0217	(0.0068,0.0367)
Capsulorrhaphy	2	0.0053	(0,0.0125)	2	0.0053	(0,0.0125)
Capsulotomy	6	0.0158	(0.0033,0.0284)	13	0.0348	(0.0162,0.0534)
Create Inframmary Fold	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	4	0.0109	(0.0003,0.0216)
Implant Reposition	6	0.0158	(0.0033,0.0284)	12	0.0321	(0.0142,0.0499)
Incision and Drainage	3	0.0078	(0,0.0166)	3	0.0078	(0,0.0166)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
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Note 3 Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	36	0.0953	(0.0657, 0.125)	40	0.1145	(0.08,0.1489)
Explant with Replacement with Study Device	23	0.0616	(0.0372,0.0861)	23	0.0616	(0.0372,0.0861)
Explant without Replacement	13	0.0354	(0.0165,0.0543)	17	0.0556	(0.0286,0.0826)
Other Reoperations	63	0.1695	(0.1313,0.2077)	65	0.1793	(0.1392,0.2194)
Biopsy	8	0.0219	(0.0069,0.0369)	8	0.0219	(0.0069,0.0369)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	1	0.0052	(0,0.0153)
Capsulectomy	11	0.0303	(0.0127, 0.048)	11	0.0303	(0.0127, 0.048)
Capsulorrhaphy	2	0.0053	(0,0.0125)	2	0.0053	(0,0.0125)
Capsulotomy	14	0.0377	(0.0183,0.0571)	14	0.0377	(0.0183,0.0571)
Create Inframmary Fold	1	0.0026	(0,0.0077)	1	0.0026	(0,0.0077)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	1	0.0028	(0,0 0083)	1	0.0028	(0,0.0083)
Implant Pocket Revision	6	0.0167	(0.0034,0.0299)	6	0.0167	(0.0034,0.0299)
Implant Reposition	15	0.0407	(0.0205,0.0609)	15	0.0407	(0.0205,0.0609)
Incision and Drainage	3	0.0078	(0,0.0166)	4	0.0131	(0,0.0267)
Mastopexy	2	0.0057	(0,0.0137)	2	0.0057	(0,0.0137)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	1	0.0026	(0,0.0078)	2	0.0054	(0,0.0129)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	2	0.0052	(0,0.0125)	2	0.0052	(0,0.0125)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	0	0.0000	(0, 0)	1	0.0027	(0,0.0081)
Scar Revision	2	0.0053	(0,0.0126)	4	0.0107	(0.0003,0.0211)
Skin Adjustment	6	0.0158	(0.0033,0.0284)	12	0.0320	(0.0142,0.0497)
Any Reoperation	30	0.0782	(0.0513, 0.105)	60	0.1572	(0.1207,0.1937)
Total Implants Assessed	386	N/A	N/A	386	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS
Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	2	0.0054	(0,0.0129)	2	0.0054	(0,0.0129)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	2	0.0052	(0,0.0125)	2	0.0052	(0,0.0125)
Revision Of Breast / External To Pocket	2	0.0058	(0,0.0138)	2	0.0058	(0,0.0138)
Revision Of Wound Closure	1	0.0027	(0,0.0081)	1	0.0027	(0,0.0081)
Scar Revision	7	0.0198	(0.0052,0.0344)	7	0.0198	(0.0052,0.0344)
Skin Adjustment	14	0.0376	(0.0183,0.0569)	14	0.0376	(0.0183,0 0569)
Any Reoperation	79	0.2089	(0.1678,0.2499)	81	0.2183	(0.1757,0.2609)
Total Implants Assessed	386	N/A	N/A	386	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	70	0.1843	(0.1453,0.2234)	93	0.2456	(0.2022, 0.289)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	17	0.0448	(0.024,0.0656)	32	0.0848	(0.0567, 0.113)
Baker III, IV Capsular Contracture	22	0.0580	(0.0345,0.0815)	36	0.0953	(0.0657, 0.125)
Baker IV Capsular Contracture	5	0.0132	(0.0017,0.0246)	7	0.0185	(0.0049,0.0322)
Breast Mass	4	0.0105	(0.0003,0.0208)	6	0.0158	(0.0033,0.0284)
Breast Pain	1	0.0026	(0,0.0078)	2	0.0053	(0,0.0126)
Breast Sensation Changes	3	0.0078	(0,0.0167)	3	0.0078	(0,0.0167)
Delayed Wound Healing	5	0.0131	(0.0017,0.0246)	5	0.0131	(0.0017,0.0246)
External Injury Not Related To Breast Implants	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Extrusion	2	0.0052	(0,0.0125)	3	0.0079	(0,0.0168)
Granuloma	2	0.0053	(0,0.0126)	2	0.0053	(0,0.0126)
Hematoma	6	0.0157	(0.0032,0.0282)	6	0.0157	(0.0032,0.0282)
Implant Malposition/Displacement	5	0.0132	(0.0017,0.0247)	6	0.0158	(0.0033,0.0284)
Infection	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Inflammation	1	0.0027	(0,0.0078)	2	0.0053	(0,0.0127)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	117	0.3130	(0.2658,0.3602)	123	0.3327	(0.2843,0.3811)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	39	0.1047	(0.0736,0.1359)	40	0.1080	(0.0763,0.1396)
Baker III, IV Capsular Contracture	42	0.1123	(0.0803,0.1444)	45	0.1228	(0.089,0.1566)
Baker IV Capsular Contracture	10	0.0269	(0.0104,0.0433)	13	0.0385	(0.0176,0.0593)
Breast Mass	9	0.0244	(0.0086,0.0403)	11	0.0311	(0.0129,0.0493)
Breast Pain	5	0.0137	(0.0018,0.0256)	5	0.0137	(0.0018,0.0256)
Breast Sensation Changes	4	0.0107	(0.0003,0.0211)	5	0.0141	(0.0018,0.0264)
Delayed Wound Healing	5	0.0131	(0.0017,0.0246)	5	0.0131	(0.0017,0.0246)
External Injury Not Related To Breast Implants	1	0.0026	(0,0.0078)	2	0.0066	(0,0.0159)
Extrusion	3	0.0079	(0,0.0168)	3	0.0079	(0,0.0168)
Granuloma	2	0.0053	(0,0.0126)	2	0.0053	(0,0.0126)
Hematoma	7	0.0186	(0.0049,0.0322)	7	0.0186	(0.0049,0.0322)
Implant Malposition/Displacement	7	0.0188	(0.005,0.0326)	7	0.0188	(0.005,0.0326)
Infection	2	0.0055	(0, 0.013)	2	0.0055	(0, 0.013)
Inflammation	2	0.0053	(0,0.0127)	2	0.0053	(0,0.0127)
Lactation Difficulties	2	0.0058	(0,0.0137)	2	0.0058	(0,0.0137)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Metastatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	1	0.0027	(0,0.0079)
Nipple Sensation Changes	15	0.0394	(0 0199, 0.059)	20	0.0527	(0.0302,0.0752)
Placement Damage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rash	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Recurrent Breast Cancer	0	0.0000	(0, 0)	1	0.0027	(0,0.0079)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	4	0.0105	(0.0003,0.0207)	4	0.0105	(0.0003,0.0207)
Suture Reaction	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	2	0.0052	(0,0.0125)	6	0.0159	(0.0033,0.0285)
Abnormal Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsular Contracture Secondary To Radiation Therapy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsule Tear	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Cellulitis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Distortion Of Breast Shape Not Related To Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Dog Ear Scars From Mastectomy	0	0.0000	(0, 0)	0	0 0000	(0, 0)
Ecchymosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excessive Implant Movements	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Metastatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	1	0.0027	(0,0.0079)	1	0.0027	(0,0.0079)
Nipple Sensation Changes	24	0.0639	(0.0392,0.0887)	25	0.0673	(0.0418,0.0928)
Placement Damage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rash	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Recurrent Breast Cancer	1	0.0027	(0,0.0079)	1	0.0027	(0,0.0079)
Rupture	4	0.0124	(0.0003,0.0246)	6	0.0202	(0.0041,0.0363)
Seroma	4	0 0105	(0 0003,0.0207)	4	0.0105	(0.0003,0.0207)
Suture Reaction	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	9	0.0249	(0.0088, 0.041)	10	0.0288	(0.011,0.0465)
Abnormal Mammogram	1	0.0029	(0,0.0086)	1	0.0029	(0,0.0086)
Capsular Contracture Secondary To Radiation Therapy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsule Tear	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Cellulitis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Distortion Of Breast Shape Not Related To Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Dog Ear Scars From Mastectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Ecchymosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excessive Implant Movements	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Extra Skin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mondor's Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Muscle Spasm	0	0.0000	(0, 0)	2	0.0053	(0,0.0127)
Nipple Complications	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Unplanned	0	0 0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pt Requests Removal Due To Personal Reasons	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Soft Mass Left Costal Margin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	0	0.0000	(0, 0)	2	0.0053	(0,0.0127)
Symmastia And Implant Malposition	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Tight Benilli Suture	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

`Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Extra Skin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	1	0.0039	(0,0.0115)
Implants Riding High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mondor's Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Muscle Spasm	2	0.0053	(0,0.0127)	2	0.0053	(0,0.0127)
Nipple Complications	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Unplanned	1	0.0033	(0,0.0097)	1	0.0033	(0,0.0097)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pt Requests Removal Due To Personal Reasons	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Siliconoma	0	0.0000	(0, 0)	1	0.0039	(0,0.0115)
Skin Lesion	1	0.0028	(0,0.0084)	1	0.0028	(0,0.0084)
Soft Mass Left Costal Margin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	2	0.0053	(0,0.0127)	2	0.0053	(0,0.0127)
Symmastia And Implant Malposition	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Tight Benilli Suture	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08 48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication Excluding Cosmetic	59	0.1552	(0.1188,0.1916)	82	0.2165	(0.175, 0.258)
II. Cosmetic Complication						
Asymmetry	1	0.0027	(0,0.0078)	3	0.0080	(0, 0.017)
Hypertrophic Scarring	9	0.0238	(0.0084,0.0391)	12	0.0318	(0.0141,0.0494)
Ptosis	2	0.0053	(0,0.0126)	3	0.0080	(0,0.0169)
Wrinkling	4	0.0106	(0.0003,0.0209)	4	0.0106	(0.0003,0.0209)
Any Cosmetic Complication	16	0.0423	(0.022,0.0626)	21	0.0556	(0.0325,0.0787)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note. Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication Excluding Cosmetic	96	0.2561	(0.2118,0.3004)	102	0.2759	(0.23,0.3217)
II. Cosmetic Complication						
Asymmetry	4	0.0107	(0.0003,0.0212)	5	0.0145	(0.0017,0.0274)
Hypertrophic Scarring	19	0.0513	(0.0288,0.0739)	19	0.0513	(0.0288,0.0739)
Ptosis	7	0.0205	(0.0054,0.0355)	7	0.0205	(0.0054,0.0355)
Wrinkling	5	0.0134	(0.0017,0.0251)	5	0.0134	(0.0017,0.0251)
Any Cosmetic Complication	34	0.0932	(0.0633,0.1232)	34	0.0932	(0.0633,0.1232)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	7	0.0183	(0.0049,0.0318)	18	0.0473	(0.026,0.0686)
Explant with Replacement with Study Device	4	0.0105	(0.0003,0.0207)	12	0.0317	(0.014,0.0493)
Explant without Replacement	3	0.0079	(0,0.0168)	6	0.0158	(0.0033,0.0284)
Other Reoperations	19	0.0500	(0.0281, 0.072)	37	0.0978	(0.0679,0.1278)
Biopsy	3	0.0079	(0,0.0169)	5	0.0132	(0.0017,0.0248)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	3	0.0079	(0,0.0168)	11	0.0293	(0.0122,0.0464)
Capsulorrhaphy	2	0.0052	(0,0.0125)	2	0.0052	(0,0.0125)
Capsulotomy	3	0.0080	(0,0.0169)	11	0.0293	(0.0122,0.0463)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	2	0.0053	(0,0.0126)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	4	0.0106	(0.0003, 0.021)
Incision and Drainage	6	0.0157	(0.0032,0.0282)	6	0.0157	(0.0032,0.0282)
Mastopexy	0	0.0000	(0, 0)	4	0.0106	(0.0003, 0.021)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7 2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	31	0.0836	(0.0554,0.1118)	39	0 1116	(0.0782, 0.145)
Explant with Replacement with Study Device	18	0.0492	(0.027,0.0714)	21	0.0608	(0.0353,0.0864)
Explant without Replacement	13	0.0353	(0.0165,0.0542)	18	0.0527	(0.0288,0.0766)
Other Reoperations	47	0.1254	(0.0919, 0.159)	58	0.1651	(0.1257,0.2045)
Biopsy	6	0.0161	(0.0033,0.0289)	7	0.0200	(0.0052,0.0348)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	12	0.0321	(0.0142, 0.05)	16	0.0470	(0.0242,0.0697)
Capsulorrhaphy	4	0.0108	(0.0003,0.0213)	4	0.0108	(0.0003,0.0213)
Capsulotomy	13	0.0348	(0.0162,0.0534)	14	0.0386	(0.0187,0.0586)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	2	0.0053	(0,0.0126)	2	0.0053	(0,0.0126)
Exploration Right Breast With Evacuation Of Hematoma	1	0.0028	(0,0.0084)	1	0.0028	(0,0.0084)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	8	0.0219	(0.0069,0.0368)	10	0.0296	(0.0113,0.0478)
Incision and Drainage	6	0.0157	(0.0032,0.0282)	6	0.0157	(0.0032,0.0282)
Mastopexy	4	0.0106	(0.0003, 0.021)	5	0.0145	(0.0017,0.0274)

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	2	0.0052	(0,0.0125)	2	0.0052	(0,0.0125)
Scar Revision	1	0.0026	(0,0.0078)	5	0.0135	(0.0017,0.0252)
Skin Adjustment	2	0.0052	(0,0.0125)	8	0.0212	(0.0067,0 0358)
Any Reoperation	26	0.0680	(0.0428,0.0933)	45	0.1179	(0 0856,0.1503)
Total Implants Assessed	383	N/A	N/A	383	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note. Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
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Table 8 7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	1	0.0035	(0,0.0104)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	1	0.0039	(0,0.0115)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	1	0.0034	(0,0.0101)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	2	0.0052	(0,0.0125)	2	0.0052	(0,0.0125)
Scar Revision	8	0.0219	(0.0069,0.0368)	9	0.0255	(0.009,0.0421)
Skin Adjustment	11	0.0295	(0.0123,0.0467)	11	0.0295	(0.0123,0.0467)
Any Reoperation	64	0.1702	(0.1321,0.2082)	77	0.2152	(0.1721,0.2584)
Total Implants Assessed	383	N/A	N/A	383	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	286	0.1513	(0.1352,0.1675)	374	0.1986	(0.1805,0.2166)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	54	0.0286	(0.0211,0.0362)	84	0.0448	(0.0355,0.0542)
Baker III, IV Capsular Contracture	61	0.0323	(0.0244,0.0403)	93	0.0496	(0.0398,0.0595)
Baker IV Capsular Contracture	7	0.0037	(0.001,0.0065)	13	0.0070	(0.0032,0.0107)
Breast Mass	6	0.0032	(0.0006,0.0057)	13	0.0070	(0.0032,0.0107)
Breast Pain	13	0.0069	(0.0031,0.0106)	15	0.0080	(0 0039, 0.012)
Breast Sensation Changes	14	0.0074	(0.0035,0.0113)	20	0.0106	(0.006,0.0152)
Delayed Wound Healing	7	0.0037	(0.001,0.0064)	7	0.0037	(0.001,0.0064)
External Injury Not Related To Breast Implants	5	0.0026	(0.0003, 0.005)	7	0.0037	(0.001,0.0065)
Extrusion	4	0.0021	(0,0.0042)	6	0.0032	(0.0006,0.0057)
Granuloma	3	0.0016	(0,0.0034)	3	0.0016	(0,0.0034)
Hematoma	20	0.0106	(0.006,0.0152)	21	0.0111	(0.0064,0.0158)
Implant Malposition/Displacement	7	0.0037	(0.001,0.0065)	10	0.0053	(0.002,0.0086)
Infection	18	0.0095	(0.0051,0.0139)	19	0.0100	(0.0056,0.0145)
Inflammation	3	0.0016	(0,0.0034)	4	0.0021	(0,0.0042)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	472	0.2543	(0.2345,0.2742)	506	0.2807	(0.2596,0.3018)
1. Complication Excluding Cosmetic						
Baker III Capsular Contracture	108	0.0586	(0.0478,0.0693)	115	0.0637	(0.0524, 0.075)
Baker III, IV Capsular Contracture	118	0.0639	(0.0527,0.0751)	127	0.0705	(0.0586,0.0825)
Baker IV Capsular Contracture	19	0.0103	(0.0057,0.0149)	24	0.0154	(0.0089, 0.022)
Breast Mass	27	0.0152	(0.0095,0.0209)	31	0.0182	(0.0118,0.0246)
Breast Pain	23	0.0127	(0.0076,0.0179)	23	0.0127	(0.0076,0.0179)
Breast Sensation Changes	24	0.0128	(0.0077, 0.018)	25	0.0136	(0.0083,0.0189)
Delayed Wound Healing	7	0.0037	(0.001,0.0064)	7	0.0037	(0.001,0.0064)
External Injury Not Related To Breast Implants	7	0.0037	(0.001,0.0065)	10	0.0069	(0.0022,0.0115)
Extrusion	6	0.0032	(0.0006,0.0057)	6	0.0032	(0.0006,0.0057)
Granuloma	3	0.0016	(0,0.0034)	3	0.0016	(0,0.0034)
Hematoma	24	0.0129	(0.0078, 0.018)	24	0.0129	(0.0078, 0.018)
Implant Malposition/Displacement	13	0.0071	(0.0032,0.0109)	13	0.0071	(0.0032,0.0109)
Infection	23	0.0123	(0.0073,0.0173)	23	0.0123	(0.0073,0.0173)
Inflammation	4	0.0021	(0,0.0042)	4	0.0021	(0,0.0042)
Lactation Difficulties	2	0.0011	(0,0.0027)	3	0.0019	(0,0.0041)
Lymphadenopathy	1	0.0005	(0,0.0016)	2	0.0016	(0, 0 004)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Metastatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	1	0.0005	(0,0.0016)
Nipple Sensation Changes	65	0.0344	(0.0262,0.0426)	94	0.0499	(0.0401,0.0598)
Placement Damage	4	0.0021	(0,0.0042)	4	0.0021	(0,0.0042)
Rash	5	0.0026	(0.0003, 0.005)	5	0.0026	(0.0003, 0.005)
Recurrent Breast Cancer	2	0.0011	(0,0.0025)	4	0.0021	(0,0.0042)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	20	0.0106	(0.006,0.0152)	20	0.0106	(0.006,0.0152)
Suture Reaction	4	0.0021	(0,0.0042)	4	0.0021	(0,0.0042)
Other	22	0.0117	(0.0068,0.0165)	31	0.0165	(0.0107,0.0223)
Abnormal Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsular Contracture Secondary To Radiation Therapy	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Capsule Tear	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Cellulitis	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Distortion Of Breast Shape Not Related To Capsular Contracture	1	0.0005	(0,0.0016)	2	0.0011	(0,0.0025)
Dog Ear Scars From Mastectomy	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Ecchymosis	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Excessive Implant Movements	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side - N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Metastatic Disease	0	0.0000	(0, 0)	2	0.0023	(0,0.0055)
Necrosis	1	0.0005	(0,0.0016)	4	0.0028	(0,0.0055)
New Diagnosis of Breast Cancer	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Nipple Sensation Changes	107	0.0572	(0.0466,0.0677)	119	0.0667	(0.055,0.0784)
Placement Damage	4	0.0021	(0,0.0042)	4	0.0021	(0,0.0042)
Rash	6	0.0032	(0.0006,0.0058)	6	0.0032	(0.0006,0.0058)
Recurrent Breast Cancer	5	0.0027	(0.0003,0.0051)	5	0.0027	(0.0003,0.0051)
Rupture	5	0.0032	(0.0004,0.0059)	8	0.0054	(0.0017,0.0092)
Seroma	22	0.0117	(0.0068,0.0166)	22	0.0117	(0.0068,0 0166)
Suture Reaction	4	0.0021	(0,0.0042)	4	0.0021	(0,0.0042)
Other	39	0.0212	(0.0146,0.0278)	45	0.0259	(0.0183,0.0335)
Abnormal Mammogram	1	0.0006	(0,0.0017)	1	0.0006	(0,0.0017)
Capsular Contracture Secondary To Radiation Therapy	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Capsule Tear	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Cellulitis	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Distortion Of Breast Shape Not Related To Capsular Contracture	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Dog Ear Scars From Mastectomy	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Ecchymosis	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Excessive Implant Movements	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	2	0.0016	(0,0.0037)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Extra Skin	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	0	0 0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Mondor's Disease	3	0.0016	(0,0.0034)	3	0.0016	(0,0.0034)
Muscle Spasm	1	0.0005	(0,0.0016)	3	0.0016	(0,0.0034)
Nipple Complications	1	0.0005	(0,0.0016)	1	0.0005	(0,0 0016)
Nipple Related Unplanned	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Pt Requests Removal Due To Personal Reasons	0	0.0000	(0, 0)	2	0.0011	(0,0.0026)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Soft Mass Left Costal Margin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	0	0.0000	(0, 0)	3	0.0016	(0,0.0034)
Symmastia And Implant Malposition	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Tight Benilli Suture	0	0.0000	(0, 0)	1	0.0005	(0,0.0016)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
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Table 8.7 2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Extra Skin	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	1	0.0008	(0,0.0023)
Implants Riding High	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Inframammay Fold Too High	1	0.0007	(0, 0.002)	1	0.0007	(0, 0.002)
Lack Of Projection	1	0.0006	(0,0.0017)	1	0.0006	(0,0.0017)
Loss Of Inframammary Fold	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Mondor's Disease	3	0.0016	(0,0.0034)	3	0.0016	(0,0.0034)
Muscle Spasm	3	0.0016	(0,0.0034)	3	0.0016	(0,0.0034)
Nipple Complications	3	0.0016	(0,0.0035)	3	0.0016	(0,0.0035)
Nipple Related Unplanned	1	0.0007	(0,0.0019)	1	0.0007	(0,0.0019)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	2	0.0016	(0,0.0037)
Pain - Sternum And Under Left Arm Intermittent	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Pt Requests Removal Due To Personal Reasons	2	0.0011	(0,0.0026)	2	0.0011	(0,0.0026)
Siliconoma	0	0.0000	(0, 0)	1	0.0008	(0,0.0023)
Skin Lesion	2	0.0011	(0,0.0026)	2	0.0011	(0,0.0026)
Soft Mass Left Costal Margin	1	0.0006	(0,0.0018)	1	0.0006	(0,0.0018)
Stitch Abscess	0	0.0000	(0, 0)	1	0.0008	(0,0.0024)
Symmastia	3	0 0016	(0,0.0034)	3	0.0016	(0,0.0034)
Symmastia And Implant Malposition	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Tight Benilli Suture	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication Excluding Cosmetic	236	0.1248	(0.1099,0.1397)	305	0.1619	(0.1452,0.1785)
II. Cosmetic Complication						
Asymmetry	12	0.0064	(0.0028,0.0099)	17	0.0090	(0.0048,0.0133)
Hypertrophic Scarring	39	0.0207	(0.0143,0.0271)	60	0.0320	(0.024,0.0399)
Ptosis	9	0.0048	(0.0017,0.0079)	12	0.0064	(0.0028, 0.01)
Wrinkling	11	0.0058	(0.0024,0.0093)	14	0.0075	(0.0036,0.0113)
Any Cosmetic Complication	68	0.0361	(0.0277,0.0445)	98	0.0522	(0.0421,0.0623)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

· Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
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Table 8 7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication Excluding Cosmetic	367	0.1972	(0.1791,0.2153)	397	0.2207	(0 2012,0.2402)
II. Cosmetic Complication						
Asymmetry	20	0.0107	(0.006,0.0154)	25	0.0147	(0.0089,0.0206)
Hypertrophic Scarring	85	0.0463	(0.0367, 0.056)	87	0.0478	(0.038,0.0577)
Ptosis	32	0.0183	(0.012,0.0246)	40	0.0251	(0.0172,0.0329)
Wrinkling	18	0.0097	(0.0052,0.0141)	19	0.0104	(0.0057, 0.015)
Any Cosmetic Complication	148	0.0810	(0.0685,0.0936)	159	0.0899	(0.0764,0.1034)

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7 SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	28	0.0148	(0.0094,0.0202)	66	0.0350	(0.0267,0.0433)
Explant with Replacement with Study Device	18	0.0095	(0.0052,0.0139)	43	0.0229	(0.0161,0.0296)
Explant without Replacement	10	0.0053	(0.002,0.0086)	23	0.0123	(0.0073,0.0173)
Other Reoperations	78	0.0413	(0.0324,0.0503)	139	0.0741	(0.0622,0.0859)
Biopsy	9	0.0048	(0.0017,0.0079)	14	0.0075	(0.0036,0.0114)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	16	0.0085	(0 0044,0.0127)	37	0.0199	(0.0135,0.0262)
Capsulorrhaphy	7	0.0037	(0.001,0.0065)	8	0 0042	(0.0013,0.0072)
Capsulotomy	12	0.0064	(0.0028, 0.01)	32	0.0171	(0.0113, 0.023)
Create Inframmary Fold	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	2	0.0011	(0,0.0026)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0 0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	4	0.0022	(0,0.0043)
Implant Reposition	8	0.0043	(0.0013,0.0072)	18	0.0096	(0.0052,0.0141)
Incision and Drainage	18	0.0095	(0.0051,0.0139)	19	0.0100	(0.0056,0.0145)
Mastopexy	1	0.0005	(0,0.0016)	5	0.0027	(0.0003, 0.005)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	101	0.0544	(0.0441,0.0647)	124	0.0716	(0.0593,0.0839)
Explant with Replacement with Study Device	61	0.0330	(0.0248,0.0411)	68	0.0386	(0.0295,0.0477)
Explant without Replacement	40	0.0219	(0.0152,0.0286)	56	0.0339	(0.0251,0.0427)
Other Reoperations	186	0.1000	(0.0864,0.1137)	212	0.1195	(0.1042,0.1347)
Biopsy	19	0.0103	(0.0057,0.0149)	20	0.0111	(0.0062,0.0159)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	1	0.0008	(0,0.0023)
Capsulectomy	50	0.0271	(0.0197,0.0345)	58	0.0335	(0.0249,0.0421)
Capsulorrhaphy	10	0.0053	(0 002,0.0087)	10	0.0053	(0.002,0.0087)
Capsulotomy	41	0.0221	(0.0154,0.0289)	44	0.0244	(0.0173,0.0316)
Create Inframmary Fold	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Excise Breast Mass	1	0.0006	(0,0.0018)	2	0.0014	(0,0.0034)
Excision Of Skin Lesion	2	0.0011	(0,0.0026)	2	0.0011	(0,0.0026)
Exploration Right Breast With Evacuation Of Hematoma	1	0.0006	(0,0.0017)	1	0.0006	(0,0.0017)
Flap Coverage Of Expander	1	0.0005	(0,0.0016)	1	0.0005	(0,0.0016)
Implant Pocket Revision	8	0.0044	(0.0014,0.0074)	8	0.0044	(0.0014,0.0074)
Implant Reposition	27	0.0146	(0.0092,0.0201)	29	0.0162	(0.0103,0.0221)
Incision and Drainage	20	0.0106	(0.006,0.0152)	21	0.0114	(0.0065,0.0163)
Mastopexy	9	0.0049	(0.0017,0.0081)	12	0.0071	(0.0031,0 0112)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	1	0.0005	(0,0.0016)	3	0.0016	(0,0.0034)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	5	0.0026	(0.0003, 0.005)	6	0.0032	(0.0006,0.0057)
Scar Revision	4	0.0021	(0,0.0042)	14	0.0075	(0.0036,0.0115)
Skin Adjustment	11	0 0058	(0.0024,0.0093)	23	0.0123	(0.0073,0.0173)
Any Reoperation	100	0 0528	(0.0428,0.0629)	178	0.0943	(0.0811,0.1075)
Total Implants Assessed	1896	N/A	N/A	1896	N/A	N/A

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side = N/A.

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Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	1	0.0007	(0,0.0022)
Nipple Related Procedure (unplanned)	3	0.0016	(0,0.0034)	4	0.0024	(0,0.0048)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	1	0.0007	(0,0.0021)
Removal Of Nodule On Chest Wall	2	0.0011	(0,0.0025)	2	0.0011	(0,0.0025)
Revision Of Breast / External To Pocket	2	0.0011	(0,0.0027)	2	0.0011	(0,0.0027)
Revision Of Wound Closure	6	0.0032	(0.0006,0.0057)	6	0.0032	(0.0006,0.0057)
Scar Revision	30	0.0165	(0.0106,0.0223)	34	0.0194	(0.0129,0.0259)
Skin Adjustment	30	0.0162	(0.0104,0.0219)	33	0.0184	(0.0122,0.0247)
Any Reoperation	244	0.1303	(0.1151,0.1456)	275	0.1528	(0 136,0 1696)
Total Implants Assessed	1896	N/A	N/A	1896	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side = N/A.

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Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS
SMOOTH SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	22	0.0574	(0.0341,0.0807)	27	0.0706	(0.0449,0.0962)	33	0.0872	(0.0588,0.1157)
Baker IV Capsular Contracture	1	0.0026	(0,0.0077)	2	0.0052	(0,0.0125)	4	0.0106	(0.0003, 0.021)
Baker III, IV Capsular Contracture	22	0.0574	(0.0341,0.0807)	27	0.0706	(0.0449,0.0962)	34	0.0899	(0.0611,0.1188)
Wrinkling	0	0.0000	(0, 0)	1	0.0026	(0,0.0078)	1	0.0026	(0,0.0078)
Total Patients Assessed	384	N/A	N/A	384	N/A	N/A	384	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS
SMOOTH SURFACE

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	35	0.0941	(0.0643,0.1239)
Baker IV Capsular Contracture	5	0.0163	(0.0012,0.0315)
Baker III, IV Capsular Contracture	36	0.0968	(0.0666, 0.127)
Wrinkling	1	0.0026	(0,0.0078)
Total Patients Assessed	384	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Note. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Table 8 7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS
TEXTURED SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0120	(0,0.0285)	4	0.0242	(0.0008,0.0477)	6	0.0365	(0.0078,0.0652)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	1	0.0061	(0,0.0181)	2	0.0123	(0,0.0292)
Baker III, IV Capsular Contracture	2	0.0120	(0,0.0285)	5	0.0303	(0.0042,0.0565)	8	0.0488	(0.0158,0.0818)
Wrinkling	1	0.0060	(0,0.0177)	1	0.0060	(0,0.0177)	3	0.0182	(0,0.0387)
Total Patients Assessed	167	N/A	N/A	167	N/A	N/A	167	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS
Creation Date, Time: 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS
TEXTURED SURFACE

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	6	0.0365	(0.0078,0.0652)
Baker IV Capsular Contracture	2	0.0123	(0,0.0292)
Baker III, IV Capsular Contracture	8	0.0488	(0.0158,0.0818)
Wrinkling	3	0.0182	(0,0.0387)
Total Patients Assessed	167	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS
SMOOTH SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	6	0.0585	(0.0131,0.1039)	6	0.0585	(0.0131,0.1039)	6	0.0585	(0.0131,0.1039)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	6	0.0585	(0.0131,0.1039)	6	0.0585	(0.0131,0.1039)	6	0.0585	(0.0131,0.1039)
Wrinkling	4	0.0392	(0.0015,0.0769)	5	0.0492	(0.0071,0.0913)	5	0.0492	(0.0071,0.0913)
Total Patients Assessed	105	N/A	N/A	105	N/A	N/A	105	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS
SMOOTH SURFACE

Type of Complication or Reoperation	36 Months (a) Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	7	0.0847	(0.0175,0.1518)
Baker IV Capsular Contracture	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	7	0.0847	(0.0175,0.1518)
Wrinkling	5	0.0492	(0.0071,0.0913)
Total Patients Assessed	105	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7 3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS
TEXTURED SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0138	(0,0.0329)	5	0.0348	(0.0048,0.0647)	9	0.0645	(0.0237,0.1053)
Baker IV Capsular Contracture	1	0.0069	(0,0.0205)	2	0.0140	(0,0.0332)	2	0.0140	(0,0.0332)
Baker III, IV Capsular Contracture	3	0.0208	(0,0.0441)	7	0.0487	(0.0135,0.0839)	11	0.0785	(0.0339,0.1231)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	146	N/A	N/A	146	N/A	N/A	146	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08.55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS
TEXTURED SURFACE

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	10	0.0762	(0.0299,0.1225)
Baker IV Capsular Contracture	2	0.0140	(0,0.0332)
Baker III, IV Capsular Contracture	12	0.0903	(0.0406, 0.14)
Wrinkling	1	0.0118	(0,0.0347)
Total Patients Assessed	146	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
REVISION PATIENTS
SMOOTH SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	9	0.0674	(0.0249,0.1099)	17	0.1279	(0.0711,0.1847)	23	0 1764	(0.1108, 0.242)
Baker IV Capsular Contracture	3	0.0224	(0,0.0476)	3	0.0224	(0,0.0476)	5	0.0382	(0.0053,0.0711)
Baker III, IV Capsular Contracture	10	0.0748	(0.0302,0.1194)	17	0.1277	(0.071,0.1844)	23	0.1762	(0.1107,0.2418)
Wrinkling	1	0.0075	(0,0.0222)	1	0.0075	(0,0.0222)	1	0.0075	(0,0.0222)
Total Patients Assessed	135	N/A	N/A	135	N/A	N/A	135	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
REVISION PATIENTS
SMOOTH SURFACE

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	23	0.1764	(0.1108, 0.242)
Baker IV Capsular Contracture	7	0.0623	(0.0163,0.1082)
Baker III, IV Capsular Contracture	24	0.1871	(0.119,0.2551)
Wrinkling	1	0.0075	(0,0.0222)
Total Patients Assessed	135	N/A	N/A

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
REVISION PATIENTS
TEXTURED SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	7	0.1007	(0.0299,0.1714)	9	0.1299	(0.0507,0.2091)	9	0.1299	(0.0507,0 2091)
Baker IV Capsular Contracture	2	0.0286	(0,0.0676)	3	0.0433	(0,0.0912)	3	0.0433	(0,0 0912)
Baker III, IV Capsular Contracture	8	0.1150	(0.04,0.1899)	10	0.1442	(0.0615,0.2269)	10	0.1442	(0 0615,0.2269)
Wrinkling	2	0.0288	(0,0.0681)	2	0.0288	(0,0.0681)	3	0.0437	(0,0.0921)
Total Patients Assessed	70	N/A	N/A	70	N/A	N/A	70	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

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Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
OVERALL PATIENTS
SMOOTH SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	37	0.0597	(0.0411,0.0784)	50	0.0812	(0.0596,0.1028)	62	0.1026	(0.0783,0.1268)
Baker IV Capsular Contracture	4	0.0064	(0.0001,0.0127)	5	0.0081	(0.001,0.0152)	9	0.0149	(0.0052,0.0246)
Baker III, IV Capsular Contracture	38	0.0613	(0.0424,0.0802)	50	0.0811	(0.0595,0.1027)	63	0.1042	(0.0798,0.1286)
Wrinkling	5	0.0081	(0.001,0.0152)	7	0.0114	(0.003,0.0197)	7	0.0114	(0.003,0.0197)
Total Patients Assessed	624	N/A	N/A	624	N/A	N/A	624	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Table 8 7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
OVERALL PATIENTS
SMOOTH SURFACE

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	65	0.1097	(0.0843, 0.135)
Baker IV Capsular Contracture	12	0.0242	(0.0098,0.0387)
Baker III, IV Capsular Contracture	67	0.1138	(0.0879,0.1397)
Wrinkling	7	0.0114	(0.003,0.0197)
Total Patients Assessed	624	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS
Creation Date, Time: 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
OVERALL PATIENTS
TEXTURED SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	11	0.0289	(0.012,0.0457)	18	0.0475	(0.0261,0.0689)	24	0.0639	(0.0392,0.0887)
Baker IV Capsular Contracture	3	0.0079	(0,0.0167)	6	0.0159	(0.0033,0.0285)	7	0.0186	(0.0049,0.0322)
Baker III, IV Capsular Contracture	13	0.0341	(0.0159,0.0523)	22	0.0581	(0.0345,0.0816)	29	0.0772	(0.0502,0.1042)
Wrinkling	3	0.0079	(0,0.0167)	3	0.0079	(0,0.0167)	6	0.0160	(0.0033,0.0287)
Total Patients Assessed	383	N/A	N/A	383	N/A	N/A	383	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time. 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.3

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL)
OVERALL PATIENTS
TEXTURED SURFACE

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	25	0.0675	(0.0418,0.0931)
Baker IV Capsular Contracture	7	0.0186	(0.0049,0.0322)
Baker III, IV Capsular Contracture	30	0.0807	(0.053,0.1085)
Wrinkling	7	0.0195	(0.0051, 0.034)
Total Patients Assessed	383	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_3.SAS Creation Date, Time: 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION
SMOOTH SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	27	0.0345	(0.0217,0.0473)	35	0.0449	(0.0303,0.0594)	45	0.0585	(0.0419,0.0751)
Baker IV Capsular Contracture	1	0.0013	(0,0.0038)	3	0.0039	(0,0.0082)	5	0.0065	(0.0008,0.0122)
Baker III, IV Capsular Contracture	28	0.0358	(0.0228,0.0488)	37	0.0475	(0.0325,0.0624)	48	0.0624	(0.0453,0.0795)
Wrinkling	0	0.0000	(0, 0)	2	0.0026	(0,0.0062)	2	0.0026	(0,0.0062)
Total Implants Assessed	783	N/A	N/A	783	N/A	N/A	783	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time. 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION
SMOOTH SURFACE

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	49	0.0652	(0.0474,0.0829)
Baker IV Capsular Contracture	7	0.0121	(0.0025,0.0218)
Baker III, IV Capsular Contracture	52	0.0690	(0.0508,0.0872)
Wrinkling	2	0.0026	(0,0.0062)
Total Implants Assessed	783	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Note 2: Implant counts exclude events where breast side = N/A.

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Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION
TEXTURED SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0058	(0,0.0138)	4	0.0117	(0.0003,0.0232)	7	0.0207	(0.0055,0.0359)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	1	0.0030	(0,0.0088)	2	0.0060	(0,0.0142)
Baker III, IV Capsular Contracture	2	0.0058	(0,0.0138)	5	0.0147	(0.0019,0.0275)	9	0.0267	(0.0095,0.0439)
Wrinkling	1	0.0029	(0,0.0086)	1	0.0029	(0,0.0086)	4	0.0118	(0.0003,0.0234)
Total Implants Assessed	344	N/A	N/A	344	N/A	N/A	344	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION
TEXTURED SURFACE

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	7	0.0207	(0.0055,0.0359)
Baker IV Capsular Contracture	2	0.0060	(0,0.0142)
Baker III, IV Capsular Contracture	9	0.0267	(0.0095,0.0439)
Wrinkling	4	0.0118	(0.0003,0.0234)
Total Implants Assessed	344	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08.55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7 4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION
SMOOTH SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	6	0.0396	(0.0085,0.0706)	7	0.0468	(0.0129,0.0807)	7	0.0468	(0.0129,0.0807)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	6	0.0396	(0.0085,0.0706)	7	0.0468	(0.0129,0.0807)	7	0.0468	(0.0129,0.0807)
Wrinkling	6	0.0398	(0.0086, 0.071)	7	0.0466	(0.0129,0.0803)	7	0.0466	(0.0129,0.0803)
Total Implants Assessed	156	N/A	N/A	156	N/A	N/A	156	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time. 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION
SMOOTH SURFACE

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	8	0.0658	(0.0161,0.1155)
Baker IV Capsular Contracture	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	8	0.0658	(0.0161,0.1155)
Wrinkling	7	0.0466	(0.0129,0.0803)
Total Implants Assessed	156	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Note. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION
TEXTURED SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0088	(0,0.0208)	6	0.0264	(0.0055,0.0472)	10	0.0450	(0.0177,0.0724)
Baker IV Capsular Contracture	1	0.0044	(0, 0.013)	2	0.0088	(0, 0.021)	2	0.0088	(0, 0.021)
Baker III, IV Capsular Contracture	3	0.0131	(0,0.0279)	8	0.0351	(0.0112,0.0591)	12	0.0538	(0.0242,0.0835)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Implants Assessed	230	N/A	N/A	230	N/A	N/A	230	N/A	N/A

Program Name. Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION
TEXTURED SURFACE

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	11	0.0520	(0.0217,0.0824)
Baker IV Capsular Contracture	2	0.0088	(0, 0.021)
Baker III, IV Capsular Contracture	13	0.0609	(0.0284,0.0933)
Wrinkling	1	0.0069	(0,0.0205)
Total Implants Assessed	230	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08.55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8 7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION
SMOOTH SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	10	0 0395	(0.0155,0.0635)	22	0.0874	(0.0525,0.1223)	29	0.1176	(0.0773,0.1579)
Baker IV Capsular Contracture	3	0.0118	(0,0.0252)	3	0.0118	(0,0.0252)	6	0.0244	(0.0051,0.0437)
Baker III, IV Capsular Contracture	13	0.0513	(0.0242,0.0785)	24	0.0952	(0.059,0.1315)	30	0.1210	(0.0803,0.1617)
Wrinkling	1	0.0040	(0,0.0117)	1	0.0040	(0,0.0117)	1	0.0040	(0,0.0117)
Total Implants Assessed	256	N/A	N/A	256	N/A	N/A	256	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION
SMOOTH SURFACE

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	30	0.1226	(0.0813,0.1638)
Baker IV Capsular Contracture	9	0.0434	(0.0149,0.0718)
Baker III, IV Capsular Contracture	33	0.1376	(0.0936,0.1817)
Wrinkling	1	0.0040	(0,0.0117)
Total Implants Assessed	256	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION
TEXTURED SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	7	0.0555	(0.0155,0.0955)	10	0.0798	(0.0323,0.1273)	10	0.0798	(0.0323,0.1273)
Baker IV Capsular Contracture	2	0.0157	(0,0.0374)	4	0.0319	(0.0011,0.0626)	4	0.0319	(0.0011,0.0626)
Baker III, IV Capsular Contracture	9	0.0713	(0.0264,0.1161)	12	0 0956	(0.0441, 0.147)	12	0.0956	(0.0441, 0.147)
Wrinkling	3	0.0239	(0,0.0506)	3	0.0239	(0,0.0506)	4	0.0321	(0.0011,0.0632)
Total Implants Assessed	127	N/A	N/A	127	N/A	N/A	127	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION
TEXTURED SURFACE

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	10	0.0798	(0.0323,0.1273)
Baker IV Capsular Contracture	4	0.0319	(0.0011,0.0626)
Baker III, IV Capsular Contracture	12	0.0956	(0.0441, 0.147)
Wrinkling	4	0.0321	(0.0011,0.0632)
Total Implants Assessed	127	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4 SAS Creation Date, Time: 24AUG04 08.55

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS
SMOOTH SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	43	0.0362	(0.0256,0.0469)	64	0.0543	(0.0413,0.0672)	81	0.0700	(0.0553,0.0847)
Baker IV Capsular Contracture	4	0.0034	(0.0001,0.0067)	6	0.0051	(0.001,0.0091)	11	0.0095	(0.0039,0.0152)
Baker III, IV Capsular Contracture	47	0.0396	(0.0285,0.0507)	68	0.0576	(0.0443,0.0709)	85	0.0733	(0.0583,0.0884)
Wrinkling	7	0.0059	(0.0015,0.0103)	10	0.0085	(0.0032,0.0137)	10	0.0085	(0.0032,0 0137)
Total Implants Assessed	1195	N/A	N/A	1195	N/A	N/A	1195	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

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Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS
SMOOTH SURFACE

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	87	0.0771	(0 0614,0.0928)
Baker IV Capsular Contracture	16	0.0178	(0.0085, 0.027)
Baker III, IV Capsular Contracture	93	0.0830	(0.0667,0.0993)
Wrinkling	10	0.0085	(0.0032,0.0137)
Total Implants Assessed	1195	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08.55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS
TEXTURED SURFACE

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	11	0.0157	(0.0065, 0.025)	20	0.0288	(0.0164,0.0412)	27	0.0392	(0.0247,0.0538)
Baker IV Capsular Contracture	3	0.0043	(0,0.0091)	7	0.0101	(0.0027,0.0176)	8	0.0116	(0.0036,0.0195)
Baker III, IV Capsular Contracture	14	0.0200	(0.0096,0.0304)	25	0.0360	(0.0221,0.0499)	33	0.0479	(0.0319,0.0638)
Wrinkling	4	0.0057	(0.0001,0.0113)	4	0.0057	(0.0001,0.0113)	8	0.0116	(0.0036,0.0196)
Total Implants Assessed	701	N/A	N/A	701	N/A	N/A	701	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS
Creation Date, Time: 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.
Note 2: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.4

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL)
OVERALL IMPLANTS
TEXTURED SURFACE

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	28	0.0411	(0.0262,0.0561)
Baker IV Capsular Contracture	8	0.0116	(0.0036,0.0195)
Baker III, IV Capsular Contracture	34	0.0498	(0.0334,0.0661)
Wrinkling	9	0.0135	(0.0047,0.0223)
Total Implants Assessed	701	N/A	N/A

Program Name Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_4.SAS Creation Date, Time: 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Note 2. Implant counts exclude events where breast side = N/A.

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Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	7	0.0814	(0.0236,0.1392)	9	0.1047	(0.04,0.1693)	14	0.1650	(0.0859,0.2442)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	1	0.0118	(0,0.0347)
Baker III, IV Capsular Contracture	7	0.0814	(0.0236,0.1392)	9	0.1047	(0.04,0.1693)	14	0.1650	(0.0859,0.2442)
Wrinkling	0	0.0000	(0, 0)	1	0.0116	(0,0.0343)	1	0.0116	(0,0.0343)
Total Patients Assessed	86	N/A	N/A	86	N/A	N/A	86	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBGLANDULAR

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	16	0.1983	(0.1098,0.2868)
Baker IV Capsular Contracture	2	0.0385	(0,0.0947)
Baker III, IV Capsular Contracture	16	0.1983	(0.1098,0.2868)
Wrinkling	1	0.0116	(0,0.0343)
Total Patients Assessed	86	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	7	0.0381	(0.0104,0.0657)	10	0.0545	(0.0216,0.0873)	11	0.0603	(0.0258,0.0949)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	1	0.0056	(0,0.0165)
Baker III, IV Capsular Contracture	7	0.0381	(0.0104,0.0657)	10	0.0545	(0.0216,0.0873)	12	0.0659	(0.0299, 0.102)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	184	N/A	N/A	184	N/A	N/A	184	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time. 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBMUSCULAR

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	11	0.0603	(0.0258,0.0949)
Baker IV Capsular Contracture	1	0.0056	(0,0.0165)
Baker III, IV Capsular Contracture	12	0.0659	(0.0299, 0.102)
Wrinkling	0	0.0000	(0, 0)
Total Patients Assessed	184	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	8	0.0705	(0.0234,0.1176)	8	0.0705	(0.0234,0.1176)	8	0.0705	(0.0234,0.1176)
Baker IV Capsular Contracture	1	0.0088	(0,0.0261)	2	0.0179	(0,0.0424)	2	0.0179	(0,0.0424)
Baker III, IV Capsular Contracture	8	0.0704	(0.0234,0.1175)	8	0.0704	(0.0234,0.1175)	8	0.0704	(0.0234,0.1175)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	114	N/A	N/A	114	N/A	N/A	114	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time. 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	8	0.0705	(0.0234,0.1176)
Baker IV Capsular Contracture	2	0.0179	(0,0.0424)
Baker III, IV Capsular Contracture	8	0.0704	(0.0234,0.1175)
Wrinkling	0	0.0000	(0, 0)
Total Patients Assessed	114	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8 7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0200	(0,0.0474)	4	0.0405	(0.0016,0.0794)	5	0.0508	(0.0074,0.0943)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	2	0.0200	(0,0.0474)	4	0.0405	(0.0016,0.0794)	5	0.0508	(0.0074,0.0943)
Wrinkling	1	0.0100	(0,0.0295)	1	0.0100	(0,0.0295)	3	0.0304	(0,0.0643)
Total Patients Assessed	100	N/A	N/A	100	N/A	N/A	100	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBGLANDULAR

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	5	0.0508	(0.0074,0.0943)
Baker IV Capsular Contracture	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	5	0.0508	(0.0074,0.0943)
Wrinkling	3	0.0304	(0,0.0643)
Total Patients Assessed	100	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08.55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	1	0.0227	(0,0.0668)	1	0.0227	(0,0.0668)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)	1	0.0227	(0,0.0668)	1	0.0227	(0,0.0668)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	45	N/A	N/A	45	N/A	N/A	45	N/A	N/A

Program Name. Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBMUSCULAR

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)
Baker IV Capsular Contracture	1	0.0227	(0,0.0668)
Baker III, IV Capsular Contracture	1	0.0227	(0,0.0668)
Wrinkling	0	0.0000	(0, 0)
Total Patients Assessed	45	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS
Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	1	0.0455	(0,0.1325)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	1	0.0455	(0,0.1325)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	2	0.0909	(0, 0.211)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	22	N/A	N/A	22	N/A	N/A	22	N/A	N/A

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
AUGMENTATION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBPECTORAL

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0455	(0,0.1325)
Baker IV Capsular Contracture	1	0.0455	(0,0.1325)
Baker III, IV Capsular Contracture	2	0.0909	(0, 0.211)
Wrinkling	0	0.0000	(0, 0)
Total Patients Assessed	22	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08.55

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - OTHER

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	1	0.1250	(0,0.3542)	1	0.1250	(0,0.3542)	1	0.1250	(0,0.3542)
Total Patients Assessed	8	N/A	N/A	8	N/A	N/A	8	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - OTHER

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)
Baker IV Capsular Contracture	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)
Wrinkling	1	0.1250	(0,0.3542)
Total Patients Assessed	8	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	3	N/A	N/A	3	N/A	N/A	3	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8 7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBGLANDULAR

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)
Baker IV Capsular Contracture	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)
Total Patients Assessed	3	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	5	0.0775	(0.0122,0.1428)	5	0.0775	(0.0122,0.1428)	5	0.0775	(0.0122,0.1428)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	5	0.0775	(0.0122,0.1428)	5	0.0775	(0.0122,0.1428)	5	0.0775	(0.0122,0.1428)
Wrinkling	2	0.0313	(0,0.0739)	3	0.0471	(0,0.0992)	3	0.0471	(0,0.0992)
Total Patients Assessed	66	N/A	N/A	66	N/A	N/A	66	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	6	0.1093	(0.0214,0.1972)
Baker IV Capsular Contracture	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	6	0.1093	(0.0214,0.1972)
Wrinkling	3	0.0471	(0,0.0992)
Total Patients Assessed	66	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7 5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0417	(0,0.1216)	1	0.0417	(0,0.1216)	1	0.0417	(0,0.1216)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	1	0.0417	(0,0.1216)	1	0.0417	(0,0.1216)	1	0.0417	(0,0.1216)
Wrinkling	1	0.0417	(0,0.1216)	1	0.0417	(0,0.1216)	1	0.0417	(0,0.1216)
Total Patients Assessed	24	N/A	N/A	24	N/A	N/A	24	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0417	(0,0.1216)
Baker IV Capsular Contracture	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	1	0.0417	(0,0.1216)
Wrinkling	1	0.0417	(0,0.1216)
Total Patients Assessed	24	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
SMOOTH SURFACE
MIXED OR UNKNOWN DEVICE PLACEMENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0 0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	4	N/A	N/A	4	N/A	N/A	4	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time. 24AUG04 08.55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
SMOOTH SURFACE
MIXED OR UNKNOWN DEVICE PLACEMENTS

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)
Baker IV Capsular Contracture	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)
Total Patients Assessed	4	N/A	N/A

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS
Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	1	0.0556	(0,0.1614)	1	0.0556	(0,0.1614)	1	0.0556	(0,0.1614)
Baker III, IV Capsular Contracture	1	0.0556	(0,0.1614)	1	0.0556	(0,0.1614)	1	0.0556	(0,0.1614)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	18	N/A	N/A	18	N/A	N/A	18	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8 7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a) Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)
Baker IV Capsular Contracture	1	0.0556	(0,0.1614)
Baker III, IV Capsular Contracture	1	0.0556	(0,0.1614)
Wrinkling	0	0.0000	(0, 0)
Total Patients Assessed	18	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time. 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0219	(0,0.0518)	5	0.0551	(0.0081, 0.102)	9	0.1034	(0.0392,0 1676)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	1	0.0112	(0,0.0331)	1	0.0112	(0,0.0331)
Baker III, IV Capsular Contracture	2	0.0219	(0,0.0518)	6	0.0662	(0.015,0.1174)	10	0.1146	(0.0475,0.1817)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	93	N/A	N/A	93	N/A	N/A	93	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS
Creation Date, Time: 24AUG04 08.55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	9	0.1034	(0.0392,0.1676)
Baker IV Capsular Contracture	1	0.0112	(0,0.0331)
Baker III, IV Capsular Contracture	10	0.1146	(0.0475,0.1817)
Wrinkling	1	0.0227	(0,0.0668)
Total Patients Assessed	93	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS

Creation Date, Time: 24AUG04 08:55

(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0 0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0 0000	(0, 0)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	33	N/A	N/A	33	N/A	N/A	33	N/A	N/A

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time. 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
TEXTURED SURFACE
DEVICE PLACEMENT - SUBPECTORAL

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0357	(0,0.1045)
Baker IV Capsular Contracture	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	1	0.0357	(0,0.1045)
Wrinkling	0	0.0000	(0, 0)
Total Patients Assessed	33	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08.55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
TEXTURED SURFACE
MIXED OR UNKNOWN DEVICE PLACEMENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	2	N/A	N/A	2	N/A	N/A	2	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
RECONSTRUCTION PATIENTS
TEXTURED SURFACE
MIXED OR UNKNOWN DEVICE PLACEMENTS

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	(0, 0)
Baker IV Capsular Contracture	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)
Total Patients Assessed	2	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time. 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
REVISION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	5	0.1220	(0.0218,0.2221)	7	0.1707	(0.0556,0.2859)	9	0.2261	(0.0955,0.3568)
Baker IV Capsular Contracture	1	0.0244	(0,0.0716)	1	0.0244	(0,0.0716)	3	0.0771	(0,0.1611)
Baker III, IV Capsular Contracture	5	0.1220	(0.0218,0.2221)	7	0.1707	(0.0556,0.2859)	9	0.2261	(0.0955,0.3568)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	41	N/A	N/A	41	N/A	N/A	41	N/A	N/A

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time. 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
REVISION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBGLANDULAR

	36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	9	0.2261	(0.0955,0.3568)
Baker IV Capsular Contracture	4	0.1140	(0.0067,0.2214)
Baker III, IV Capsular Contracture	10	0.2584	(0.1187, 0.398)
Wrinkling	0	0.0000	(0, 0)
Total Patients Assessed	41	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08:55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT
REVISION PATIENTS
SMOOTH SURFACE
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	3	0.0407	(0,0.0859)	7	0.0958	(0.0283,0.1632)	10	0.1393	(0.0591,0.2195)
Baker IV Capsular Contracture	1	0.0135	(0,0.0398)	1	0.0135	(0,0.0398)	1	0.0135	(0,0.0398)
Baker III, IV Capsular Contracture	3	0.0405	(0,0.0855)	7	0.0956	(0.0282,0.1629)	10	0.1391	(0.059,0.2192)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	75	N/A	N/A	75	N/A	N/A	75	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7_5.SAS Creation Date, Time: 24AUG04 08.55
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptablely low sensitivity, breast-unacceptablely low/high sensitivity, nipple complications, and wrinkling.